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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,706	02/25/2002	Theodore H. Suprak	N1305-025	5310

32905 7590 04/03/2003

JONDLE & ASSOCIATES P.C.  
9085 EAST MINERAL CIRCLE  
SUITE 200  
CENTENNIAL, CO 80112

EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

10/082,706

Applicant(s)

SUPERAK ET AL.

Examiner

Anne R. Kubelik

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1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_ .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

### **DETAILED ACTION**

1. Claims 1-33 are pending.

#### ***Claim Objections***

2. Claims 1, 7, 9 and 18 are objected to for the inclusion of a blank line where the ATCC Accession number should be.

3. Claims 8, 18, 23, 29 and 33 are objected to because of the following informalities:

In claim 8, lines 1-2, either "protoplast" should be plural or "calli" should be singular.

There is a period at the start of claim 18.

In claims 23 and 29, line 3, "::" should be placed with a single colon.

In claim 33, line 3, "::" should be placed with a single colon and "835traits" should be replaced with --835 traits--.

4. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 is drawn to a squash plant of claim 2, wherein the plant is male sterile. Claim 2 is drawn to a squash plant produced by growing a particular seed line. The plant of claim 2 is not male sterile (see the specification in paragraph 0050, where the plant was self-pollinated). Thus, the plant of claim 6 is broader than the plant of claim 2, and claim 6 fails to further limit claim 2.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 6, 11-13, 15-17 and 19-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to squash plants and methods of producing squash plants that involve an indeterminate number of generations and parent plants or of introduced transgenes of unknown function and number, wherein it remains unclear what the identity of the plants in each of the steps would be, much less what the resultant product plant would be. Neither the plants required by each of the steps, nor the plants that are produced by the process are defined by genomic structure or by all their phenotypic characteristics, and therefore, the claimed invention lacks an adequate written description.

See *University of California v. Eli Lilly*, 119 F.3d 1567, 43 USPQ 2d 1405 (Fed. Cir. 1997), where it states:

[a] written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, and given the high level of unpredictability in this art, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

7. Claims 1-33 are rejected under 35 USC 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the seed claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that Applicant intends to deposit seeds for 835 at the ATCC, but there is no indication that the seeds have been deposited and there is no indication in the specification as to public availability. If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

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(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 1, 7, 9 and 18 are indefinite in their recitation of "ATCC Accession No. \_\_\_\_\_", because the ATCC Accession No. is missing.

Claim 1 is indefinite in its recitation of "an inbred squash seed designated 835", claim 7 is indefinite in its recitation of "inbred 835", claims 7, 9 and 18 are indefinite in their recitation of "inbred squash line 835", claims 18-23 are indefinite in their recitation of "835-derived", claims 19, 21, 23, 29 and 33 are indefinite in their recitation of "835 traits", and claim 25 is indefinite in its recitation of "line 835", given that a name does not clearly identify the claimed squash cultivar and seed, and does not set forth the metes and bounds of the claimed invention. Since the name 835 is not known in the art, the use of said name does not carry art recognized limitations as to the specific characteristics or essential characteristics that are associated with that denomination. In addition, the name appears to be arbitrary, and the specific characteristics associated therewith could be modified, as there is no written description of the squash plant that encompasses all of its traits. Amending the claims to recite the ATCC deposit number would overcome the rejection.

Claim 6 is indefinite because it is unclear what physiological or morphological characteristics of the plant of claim 2 have been altered to produce the male sterile plant. Male sterility can be the result of many different physiological and/or morphological changes.

Claim 7 lacks antecedent basis for the limitation “the tissue” in lines 1-2. It is also unclear how tissue can regenerate plants; plants can, however, be regenerated from tissue.

Claims 7 and 9 are indefinite in their recitation of “capable of expressing”. It is not clear if the plant actually does express all these characteristics. It is suggested that the phrase be replaced with --having--.

Claim 18 is indefinite in that it is drawn to producing a squash variety 835-derived squash plant by crossing said plant with a second squash plant to produce progeny seed. However, it remains unclear if the claim is drawn only to the production of progeny that is an F1 hybrid seed, or if it may encompass additional generations of progeny that are derived from these two parents.

In claims 18 and 20, part (b), the phrase “under plant growth conditions” is meaningless because Applicant has not defined appropriate plant growth conditions. The phrase should be deleted.

Claims 19, 21, 23, 29 and 33 are indefinite in their recitation of “an extended mid season harvest”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 19, 21, 23, 29 and 33 are indefinite in their recitation of “large plant”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the

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specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 19, 21, 23, 29 and 33 are indefinite in their recitation of “average open habit”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 19, 21, 23, 29 and 33 are indefinite in their recitation of “medium green to dark green”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 19, 21, 23, 29 and 33 are indefinite in their recitation of “tolerant”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 19, 21, 23, 29 and 33 are indefinite in their recitation of “adapted to Eastern United States, Mexico, France and Italy”, since the metes and bounds of Eastern United States is not clearly defined and are subject to different interpretation, and given that is unclear what it means for the plant to be “adapted” to each of these regions. The specification fails to define or clarify the use of these terms. Therefore, the characteristics of the claimed plant remain unclear.

In claim 22, the method step “utilizing plant tissue culture methods to derive progeny” is indefinite. The claim should be amended to clearly define the additional method steps.



Claims 24-25 are indefinite in their recitation of a squash plant containing “one or more transgenes”, since it is unclear how many new traits the claimed plant would exhibit, and it remains unclear what the phenotype of the claimed plant would be.

In claims 24-25, it is unclear if the transgenes are operably linked to the same regulatory element or if each transgene has its own regulatory element.

Claims 27-28 are indefinite because they lack clear positive method steps. The method step “employing a squash plant” does not recite clearly defined positive method steps. In claim 27 it is unclear what method steps are involved in the method for developing a squash plant other than obtaining the squash plant. Additionally, it is unclear to which squash plant, the one developed or the one employed, that step refers. In claim 28, it is unclear how many of the plant breeding techniques would be used and in what combinations. Again, the method steps are not clearly defined. For example, it is uncertain for each of the recited breeding techniques what steps they would be comprised of, how many generations of crosses would be incorporated in the method, and what parent plants would be used for each cross.

Claims 31-32 lack antecedent basis for the limitation “the gene” in line 1.

***Claim Rejections - 35 USC § 102 - 35 USC § 103***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 6, 11-13, 15-17 and 19-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Miller et al (US Patent 6,031,158).

Applicant has claimed plants derived from 835 squash after one or more crosses and using unspecified second parents and methods of making those plants. In addition, some of the claims specify that at least two designated characteristics would be present in the claimed squash. However, it appears that the claimed plants and seeds are the same as the prior art hybrid squash seeds deposited as ATCC Accession No. PTA-866 and plants grown from the seeds, given that each is a large plant and bears medium green to dark green cylindrical fruits, for example. Alternatively, if the claimed plants and seeds of the instant invention are not identical to hybrid squash seeds deposited as ATCC Accession No. PTA-866 and plants grown from the seeds, then it appears that hybrid squash seeds deposited as ATCC Accession No. PTA-866 and plants grown from the seeds only differ from the claimed plants and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to 835-derived plants. Similarly, the methods of crossing 835-derived squash would be the same as the methods of crossing prior art hybrid squash grown from seed deposited as ATCC Accession No. PTA-866. Thus the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by hybrid squash grown from seed deposited as ATCC Accession No. PTA-866 and methods of their use.

13. Claims 6, 11-13, 15-17 and 19-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Superak (US Patent 5,959,184).

Applicant has claimed plants derived from 835 squash after one or more crosses and using unspecified second parents and methods of making those plants. In addition, some of the claims specify that at least two designated characteristics would be present in the claimed squash. However, it appears that the claimed plants and seeds are the same as the progeny of prior art squash cultivar G19, given that each is resistant to Zucchini Yellow Mosaic Virus, for example. Alternatively, if the claimed plants and seeds of the instant invention are not identical to progeny of prior art squash cultivar G19, then it appears that progeny of prior art squash cultivar G19 only differ from the claimed plants and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to 835-derived plants. Similarly, the methods of crossing 835-derived squash would be the same as the methods of crossing progeny of prior art squash cultivar G19. Thus the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by progeny of prior art squash cultivar G19 and methods of their use.

### ***Double Patenting***

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 6, 11-13, 15-17 and 19-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 11-13, 15-17 and 19-33 of copending Application No. 10/082,707. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instantly claimed plants are derived from 835 squash after one or more crosses and using unspecified second parents and methods of making those plants. In addition, some of the claims specify that at least two designated characteristics would be present in the claimed soybean. However, it appears that the claimed plants and seeds are the same as 833-derived squash plants or 833 squash plants themselves, as claimed in the copending application, given that each has resistance to Zucchini Yellow Mosaic Virus and an extended mid-season harvest, for example. Alternatively, if the claimed plants and seeds of the instant invention are not identical to 833-derived squash plants or 833 squash plants themselves, claimed in the copending application, then it appears that 833-derived squash plants or 833 squash plants themselves only differ from the claimed plants and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to 835. Similarly, the methods of crossing 835-derived squash would be the same as the methods of crossing 833-derived squash plants or 833 squash plants themselves, claimed in the copending application. Thus, the 833-derived squash plants or 833 squash plants themselves,

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claimed in the copending application, and methods of their use are species of the genus of 835-derived squash plants claimed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Conclusion*

16. No claim is allowed.

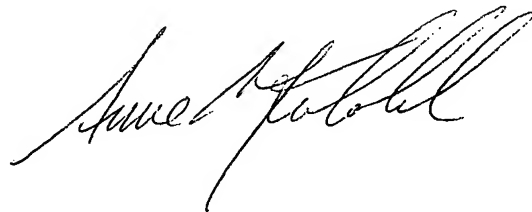
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.

April 1, 2003

A handwritten signature in cursive script, appearing to read "Anne R. Kubelik", written in black ink.